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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CHIESI USA, INC. and CHIESI FARMACEUTICI S.P.A. Plaintiffs, v. AUROBINDO PHARMA USA, INC. and AUROBINDO PHARMA LTD. Defendants.	)	C.A. No. _____ *Document Filed Electronically*

COMPLAINT

Plaintiffs Chiesi USA, Inc. and Chiesi Farmaceutici S.p.A. (collectively, "Chiesi" or "Plaintiffs") by its undersigned attorneys, for its Complaint against defendants Aurobindo Pharma USA, Inc. ("Aurobindo USA") and Aurobindo Pharma Ltd. ("Aurobindo Ltd.") (collectively, "Aurobindo" or "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 8,658,676 ("the '676 patent") (attached as Exhibit A hereto) and U.S. Patent No. 10,010,537 ("the '537 patent") (attached as Exhibit B hereto) (collectively, the "patents in suit").

THE PARTIES

2. Chiesi USA, Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 175 Regency Woods Place, Suite 600, Cary, North Carolina 27518. Chiesi USA, Inc. is a wholly owned subsidiary of Chiesi Farmaceutici S.p.A.

3. Chiesi USA, Inc. is the owner of New Drug Application ("NDA") No. 022156, which was approved by the U.S. Food and Drug Administration ("FDA") for the manufacture and sale of Cleviprex® (clevidipine) injectable emulsion.

4. Chiesi Farmaceutici S.p.A. is a corporation organized and existing under the laws of Italy, having its principal place of business at Via Palermo, 26/A, 43122 Parma, Italy.

5. Chiesi Farmaceutici S.p.A. is the current owner and assignee of each of the three (3) patents listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Chiesi's Cleviprex®, of which two (2) are the patents in suit. The two (2) patents in suit were previously owned by The Medicines Company, on assignment from the inventors, who were employees of The Medicines Company. Upon information and belief, The Medicines Company is a corporation having its principal place of business in Parsippany, New Jersey, which is in this Court's Newark vicinage. Upon information and belief, one of the inventors of the patents in suit works in Parsippany, New Jersey.

6. Upon information and belief, Aurobindo USA is a corporation organized under the laws of Delaware, having its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520 and a pharmaceutical distribution center at 6 Wheeling Road, East Windsor, New Jersey 08520.

7. Upon information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd. Aurobindo Ltd.'s website lists Aurobindo USA as one of its fully owned "International[] Subsidiaries."[1]

8. Upon information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Service to do business in the State of New Jersey under entity ID No. 0100921223.

9. Upon information and belief, Aurobindo USA is in the business of, among other things, the development, manufacturing, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey. Aurobindo USA's website states that recently "Aurobindo Pharma USA opened its doors to new-state-of-the-art warehouse and distribution center[, l]ocated in central New Jersey[.]"[2]

10. Upon information and belief, Aurobindo Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad - 500084, Telangana, India.

11. Upon information and belief, Aurobindo Ltd. is registered with the State of New Jersey's Division of Revenue and Enterprise Service to do business in the State of New Jersey under entity ID No. 0100904116.

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[1] Global Operations Map, https://www.aurobindo.com/about-us/at-a-glance/global-operations-map/ (last visited Sept. 24, 2019).

[2] Aurocontrol, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last visited Sept. 24, 2019).

12. Upon information and belief, Aurobindo USA is an authorized U.S. Agent for Aurobindo Ltd. Upon information and belief, Aurobindo USA acts at the direction, and for the benefit, of Aurobindo Ltd., and is controlled and/or dominated by Aurobindo Ltd.

13. Upon information and belief, Aurobindo USA is an authorized U.S. Agent for Aurobindo Ltd. with respect to Abbreviated New Drug Applications ("ANDAs") submitted to the FDA pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), including at least ANDA No. 213280 (Clevidipine injectable emulsion, 25 mg/ 50 mL and 50 mg/ 100 mL) ("Aurobindo's ANDA"). Upon information and belief, Aurobindo's ANDA included a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A) ("paragraph IV certification") to the patents in suit.

14. Upon information and belief, Aurobindo Ltd., by itself and/or through its wholly owned subsidiaries, is in the business of, among other things, the development, manufacturing, and importation of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in New Jersey.

15. Upon information and belief, Defendants operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

16. Upon information and belief, Defendants operate as a single integrated business with respect to the regulatory approval, manufacturing, importation, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in New Jersey. Aurobindo Ltd.'s website states that it is a "well-integrated pharma company" with

"multiple facilities approved by leading regulatory agencies such as USFDA[.]"[3] Aurobindo USA's website states that it is a "truly integrated company" involving, among other things, the manufacture, marketing, sale and distribution of its generic pharmaceutical products.[4]

17. Upon information and belief, Defendants derive substantial revenue from the sale of generic pharmaceutical products throughout the United States, including in New Jersey.

18. Upon information and belief, Defendants have submitted Aurobindo's ANDA to the FDA, seeking approval to market clevidipine injectable emulsion, 25 mg/ 50 mL and 50 mg/ 100 mL (the "ANDA Product") throughout the United States, including in New Jersey, before the expiration of the patents in suit.

JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

20. This Court has personal jurisdiction over Aurobindo USA at least because, upon information and belief: (i) Aurobindo USA's principal place of business is located in New Jersey; (ii) Aurobindo USA is doing business in New Jersey and maintains continuous and systematic contacts with New Jersey; (iii) Aurobindo USA, together with its parent Aurobindo Ltd., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Aurobindo USA, together with Aurobindo Ltd., has committed, induced, or contributed to acts of patent infringement in New Jersey; (v) Aurobindo USA has previously submitted to the jurisdiction of this Court and

[3] Business Overview, https://www.aurobindo.com/about-us/at-a-glance/business-overview/ (last visited Sept. 24, 2019).

[4] *See* Aurocontrol, https://www.aurobindousa.com/company/our-story/aurocontrol/ (last visited Sept. 24, 2019).

has availed itself of New Jersey's legal protections in at least four (4) prior litigations and previously consented to personal jurisdiction and venue in New Jersey.[5]

21. This Court has personal jurisdiction over Aurobindo Ltd. at least because, upon information and belief: (i) Aurobindo Ltd. manufactures generic pharmaceutical products that are imported, distributed, and sold throughout the United States and thus avails itself of the privileges and benefits of the laws and commerce of the United States and New Jersey; (ii) Aurobindo Ltd. is doing business in New Jersey and maintains continuous and systematic contacts with New Jersey; (iii) Aurobindo Ltd. is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, and in partnership or agency with its subsidiary Aurobindo USA for importation, sale, and/or distribution in the State of New Jersey; (iv) Aurobindo Ltd. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in New Jersey; (v) Aurobindo Ltd., together Aurobindo USA, has committed, induced, or contributed to acts of patent infringement in New Jersey; and (vi) Aurobindo Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of New Jersey's legal protections in at least four (4) prior litigations.[6]

22. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if Aurobindo's ANDA receives final FDA approval, the ANDA Product

[5] *Celgene Corp.*v. *Aurobindo Pharma Ltd. et al*, No. 2:19-cv-0143 (D.N.J. filed Jan. 4, 2019); *Forest Labs., LLC et al* v. *Aurobindo Pharma USA, Inc. et al*, No. 2:17-cv-11679 (D.N.J. filed Nov. 15, 2017); *Boehringer Ingelheim Pharma., Inc. et al* v. *Aurobindo Pharma USA, Inc. et al*, No. 3:17-cv-07887 (D.N.J. filed Nov. 27, 2017); *Mitsubishi Tanabe Pharma Corp. et al* v. *Aurobindo Pharma USA, Inc. et al*, No. 3:17-cv-05005 (D.N.J. filed July 7, 2017).

[6] *Celgene Corp.* v. *Aurobindo Pharma Ltd. et al*, No. 2:19-cv-05799 (D.N.J. filed Feb. 14, 2019); *Sumitomo Daonippon Pharma Co. et al* v. *Aurobindo Pharma Ltd. et al*, No. 2:18-cv-02620 (D.N.J. filed Feb, 23, 2018); *Forest Labs., LLC et al* v. *Prinston Pharma. Inc. et al*, No. 2:17-cv-10230 (D.N.J. filed Oct. 31, 2017); *Janssen Prods., L.P. et al* v. *Aurobindo Pharma Ltd. et al*, No. 2:17-cv-06872 (D.N.J. filed Sept. 7, 2017).

will be manufactured, sold, distributed, and/or used by Defendants in New Jersey, prescribed by physicians practicing in New Jersey, and/or administered to patients in New Jersey.

23. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), and/or 1400(b).

24. Federal venue rules do not restrict the locations in which alien corporations, like Aurobindo Ltd., may be sued. *In re HTC Corp.*, 889 F.3d 1349, 1354–61 (Fed. Cir. 2018) (citing *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706 (1972); and *In re Hohorst*, 150 U.S. 653 (1893)). For that reason, venue is proper in this Court.

FACTS AS TO ALL COUNTS

25. Chiesi's Cleviprex® is sold and marketed under NDA No. 022156.

26. NDA No. 022156 pertains to Cleviprex® 25 mg/ 50 mL and 50 mg/ 100 mL vial presentations.

27. Chiesi's Cleviprex® is "a sterile, milky-white emulsion containing 0.5 mg/mL of clevidipine suitable for intravenous administration."

28. Chiesi's Cleviprex® is indicated for "the reduction of blood pressure when oral therapy is not feasible or not desirable."

29. FDA's Orange Book lists three (3) patents as covering Chiesi's Cleviprex®: the '676 patent, the '537 patent, and U.S. Patent No. 5,856,346 ("the '346 patent").

30. Defendants sent a letter addressed to Chiesi USA, Inc. and Chiesi Farmaceutici S.p.A., dated August 23, 2019, purportedly pursuant to § 505(j)(2)(A)(iv) of the FD&C Act, 21 U.S.C. § 355(j)(2)(A)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations, regarding Aurobindo's ANDA (the "Notice Letter").

31. The Notice Letter states that Aurobindo's ANDA has been submitted under § 505(j) of the FDCA, with a paragraph IV certification to obtain approval to engage in the

commercial manufacture, use, sale, and/or distribution of an injectable emulsion containing 25 mg/ 50 mL and 50 mg/ 100 mL of clevidipine, before the expiration dates of the patents in suit: the ’676 patent and the ’537 patent. As indicated in the Orange Book, the patent expiration for the ’676 patent and the ’537 patent is October 10, 2031.

32. Upon information and belief, Aurobindo’s ANDA was submitted under § 505(j) of the FDCA with a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’676 patent and the ’537 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the ANDA Product.

33. Upon information and belief, the prescribing information for the ANDA Product will recommend the same Indication and Usage as Cleviprex®.

34. Upon information and belief, the prescribing information for the ANDA Product will recommend the same Dosage and Administration as Cleviprex®.

35. Upon information and belief, administration of the ANDA Product, like Cleviprex®, will be used for the reduction of blood pressure when oral therapy is not feasible or not desirable.

36. The ’676 patent, titled “Clevidipine Emulsion Formulations Containing Antimicrobial Agents,” was duly and legally issued by the U.S. Patent and Trademark Office on February 25, 2014, to The Medicines Company on assignment from inventors Rajeshwar Motheram and Gregory Charles Williams. Subsequently, The Medicines Company assigned the ’676 patent to Chiesi Farmaceutici S.p.A.

37. The ’537 patent, titled “Clevidipine Emulsion Formulations Containing Antimicrobial Agents,” was duly and legally issued by the U.S. Patent and Trademark Office on July 3, 2018, to The Medicines Company on assignment from inventors Rajeshwar Motheram

and Gregory Charles Williams. Subsequently, The Medicines Company assigned the '537 patent to Chiesi Farmaceutici S.p.A.

38. Pursuant to 21 U.S.C. § 355(b)(1), the '676 patent and the '537 patent were submitted to FDA with NDA No. 022156. The '676 patent and the '537 patent were subsequently listed in the Orange Book as covering Cleviprex®.

39. But for the expiration of any patent for which certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) has been made, any final approval of Aurobindo's ANDA shall be effective no earlier than February 23, 2022. *See* 21 U.S.C. § 355(c)(3)(C).

40. The Notice Letter does not state that Aurobindo's ANDA contains a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '346 patent.

41. Defendants did not send a letter to Chiesi stating that Aurobindo's ANDA contains a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '346 patent

42. Upon information and belief, Aurobindo's ANDA does not contain a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '346 patent.

43. Upon information and belief, Defendants are not seeking final FDA approval of Aurobindo's ANDA before the expiration of the '346 patent. As indicated in the Orange Book, the patent expiration for the '346 patent is January 5, 2021.

FIRST COUNT

(Defendants' Infringement of the '676 patent)

44. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

45. Upon information and belief, Defendants prepared Aurobindo's ANDA.

46. Upon information and belief, Defendants submitted Aurobindo's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit.

47. Upon information and belief, Aurobindo's ANDA is based upon Cleviprex® injectable emulsion, 25 mg/ 50 mL and 50 mg/ 100 mL, as its reference listed drug.

48. Upon information and belief, the ANDA Product is clevidipine injectable emulsion, 25 mg/ 50 mL and 50 mg/ 100 mL.

49. Upon information and belief, Defendants submitted Aurobindo's ANDA with a paragraph IV certification to the '676 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '676 patent.

50. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

51. Upon information and belief, as of the date of the Notice Letter Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

52. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA, Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

53. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of Aurobindo's ANDA with a paragraph IV certification to the '676 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '676 patent is an act of infringement of the '676 patent.

54. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if Aurobindo's ANDA ever receives final FDA approval.

55. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '676 patent's claims under 35 U.S.C. § 271.

56. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '676 patent under 35 U.S.C. § 271.

57. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

58. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SECOND COUNT

(Defendants' Infringement of the '537 patent)

59. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

60. Upon information and belief, Defendants prepared Aurobindo's ANDA.

61. Upon information and belief, Defendants submitted Aurobindo's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patents in suit.

62. Upon information and belief, Aurobindo's ANDA is based upon Cleviprex® injectable emulsion, 25 mg/ 50 mL and 50 mg/ 100 mL, as its reference listed drug.

63. Upon information and belief, the ANDA Product is clevidipine injectable emulsion, 25 mg/ 50 mL and 50 mg/ 100 mL.

64. Upon information and belief, Defendants submitted Aurobindo's ANDA with a paragraph IV certification to the '537 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '537 patent.

65. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the

factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

66. Upon information and belief, as of the date of the Notice Letter Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

67. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Defendants sent a copy of the Notice Letter to Chiesi USA, Inc. at 175 Regency Woods, Suite 600, Cary, North Carolina 27518 and another copy of the Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma 43122, Italy.

68. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of Aurobindo's ANDA with a paragraph IV certification to the '537 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '537 patent is an act of infringement of the '537 patent.

69. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if Aurobindo's ANDA ever receives final FDA approval.

70. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '537 patent's claims under 35 U.S.C. § 271.

71. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product will induce and/or contribute to third-party infringement of one or more claims of the '537 patent under 35 U.S.C. § 271.

72. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

73. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment declaring that the '676 patent is valid and enforceable;

(B) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '676 patent by submitting to FDA Aurobindo's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '676 patent;

(C) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '676 patent (including any regulatory extension), would directly and/or indirectly infringe the '676 patent;

(D) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Aurobindo's ANDA shall be no earlier than the date on which the '676 patent expires (including any regulatory extension);

(E) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and

any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '676 patent (including any regulatory extension);

(F) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Plaintiffs damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of Aurobindo's ANDA, prior to the expiration of the '676 patent (including any regulatory extension);

(G) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '676 patent is willful and awarding Plaintiffs enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of Aurobindo's ANDA, prior to the expiration of the '676 patent (including any regulatory extension);

(H) A judgment declaring that the '537 patent is valid and enforceable;

(I) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants infringed the '537 patent by submitting to FDA Aurobindo's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '537 patent;

(J) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '537 patent (including any regulatory extension), would directly and/or indirectly infringe the '537 patent;

(K) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of the ANDA shall be no earlier than the date on which the '537 patent expires (including any regulatory extension);

(L) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '537 patent (including any regulatory extension);

(M) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Plaintiffs damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of Aurobindo's ANDA, prior to the expiration of the '537 patent (including any regulatory extension);

(N) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Defendants' infringement of the '537 patent is willful and awarding Plaintiffs enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of Aurobindo's ANDA, prior to the expiration of the '537 patent (including any regulatory extension);

(O) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Plaintiffs their attorneys' fees and costs;

(P) Such other and further relief as this Court may deem just and proper.

Dated: October 7, 2019

Respectfully submitted,

By: /s/ Charles H. Chevalier

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